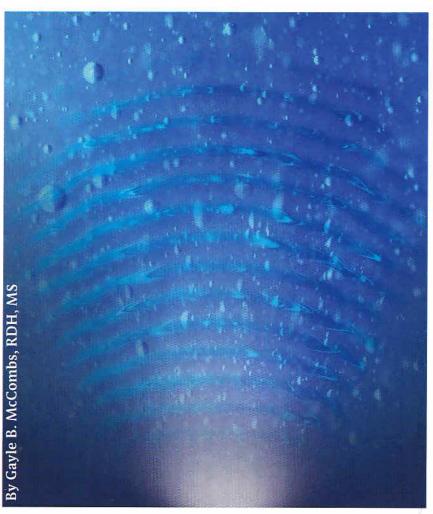
# **Exhibit T**



# **Ultrasound Technology** Fransitioning into Ora Care and Beyond



# A Dimensions of Dental Hygiene Continuing Education Course Available In Print and Online

This course was developed in part with an unrestricted educational grant from Ultreo, Inc.



# A Peer Reviewed Publication

Vew Correspondence CE Courses Designed for Dental Professionals







## **Educational Objectives**

After reading this course, the participant should be able to:

- 1. Discuss the evolution of ultrasound in medicine and dentistry.
- 2. Compare and contrast sonic, ultrasonic, and ultrasound technologies.
- 3. Explain frequency range differences among mechanical, rotary, sonic, and ultrasonic power toothbrushes.
- 4. Describe the differences in brush strokes and/or pulsations among the various power toothbrushes.
- 5. Discuss current research as it relates to the ultrasound toothbrush.
- 6. Explain the advantages of combined sonic and ultrasound technology.
- 7. Discuss the variations in brush stroke and/or pulsations among the different power toothbrushes.

LTRASOUND TECHNOLOGY HAS EVOLVED OVER THE PAST 100 YEARS, FROM THE discovery of underwater sonar detection to the transfer of this technology into industry, medicine, and dentistry. Medical ultrasound has transitioned into almost every aspect of therapeutic, diagnostic, and operative care. However, the use of ultrasound in dentistry has not advanced as quickly or as broadly. In the dental field, ultrasound technology has progressed from instrument cleaning to the leader in the mechanical removal of calcified deposits and the disruption of plaque biofilm. The use of this technology has the potential to extend beyond debridement, into a new realm of oral care for the 21st century.

### BRIEF HISTORY OF ULTRASOUND

The evolution of ultrasound technology spans over a century. What began as simple echo sounding methods in 1880 led to the discovery of sound navigating and ranging (SONAR) and nondestructive metal-flaw detection.1 The first SONAR apparatus was developed in the early 1900s to help mariners measure depth and distance while navigating deep waters (see Figure 1). SONAR became especially important after the sinking of the Titanic in 1912 and during World Wars I and II for the detection of submarines and large submerged objects.

Between the wars, the diagnostic capability of ultrasound technology was applied to solids as metal flaw detection systems. Used to assess the integrity of solid materials, the first commercial flaw detector was marketed in the United States in 1945.<sup>1,2</sup> Metal flaw detection is commonly used to assess thickness, as well as to identify cracks, corrosion, and other imperfections in the hulls of ships and aerospace vehicles. Both of these military and industrial applications of SONAR and metal flaw detection are considered milestones in technology and a precursor to modern medical ultrasound

The transition of ultrasound to medicine has been unremitting and collaborative over the past 3 decades. Karl T. Dussik, MD, a physician in Vienna, first wrote about the use of ultrasound as a medical diagnostic tool in the 1940s.1 After learning about underwater ultrasound, Dussik became fascinated with this technology and embarked on a lifelong journey to expand its diagnostic capabilities in medicine. Dussik, whose father was a practicing dentist, is considered by many to be the father of ultrasound. Some of Dussik's earliest experiments explored the use of ultrasound beams projected through the head to locate brain tumors and other abnormalities.

Other luminaries in the development of medical ultrasound were George Ludwig, MD, for his groundbreaking work in detecting the presence and position of foreign bodies in humans, John Wild, MD, for the development of an early ultrasonic breast cancer detection system in the 1950s, and Ian Donald, MD, for his work with the development of the two-dimensional scanner in 1960.

Initially, ultrasound applications were used for therapy rather than diagnostics, but during the 1940s and 1950s a tremendous amount of research was dedicated to expanding the use of this technology. In the ensuing years, many researchers, clinicians, and engineers worked together to make dramatic

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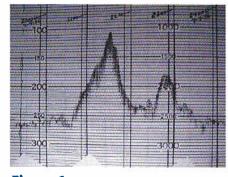


Figure 1. SONAR image from Navy manual.

changes in material, size, and image

As technology improved and computer power and capacity increased, diagnostic and therapeutic applications expanded into numerous areas of medicine. For instance, ultrasound scanning is used to detect kidney stones and focused ultrasound may be used to break up the stones into small pieces that can easily be eliminated in the urine. Physical therapists use ultrasound as a noninvasive thermal or nonthermal modality for management of soft tissue disorders, such as pain in joints and muscles, as well as to ease discomfort associated with arthritis and bursitis. Cardiologists and internists use a broad array of ultrasound systems to image and diagnose conditions of the heart and great vessels, such as valvular heart disease, congenital heart disease, and ischemic heart disease. Furthermore, obstetricians routinely use fetal ultrasound, also known as fetal sonography, at 16 to 18 weeks to provide detailed images of the developing fetus and the uterus (see Figure 2, page 4).

More recently, the physiological effects of ultrasound have been studied as a way to stimulate bone growth and healing.3,4 Although the exact mechanism of action is unclear, researchers continue to investigate low-intensity ultrasound's effect on bone regeneration associated with joint replacements,

## **GLOSSARY OF TERMS**

Acoustic: The scientific study of sound, a disturbance of energy (vibration) within a medium, that includes vibrations or frequencies above the range of human hearing. Sound is characterized by properties such as frequency, wavelength, amplitude, and speed.

Audible: Frequencies occurring between 20 Hz and 20,000 Hz. Typical voice frequency ranges from 250 Hz-3,500 Hz.

Cavitation: The sequential formation, pulsation, and/or collapse of vapor bubbles and voids in a liquid subjected to acoustic energy at high frequency and intensity.

Hz: Hertz is a unit of frequency related to one cycle per second. Kilohertz (kHz or KHz) is a unit equal to 1,000 Hz. MHz is equal to 1,000,000 Hz or 1,000 kHz.

**Sonic:** Frequencies within the audible range of the human ear (20-20,000 Hz).

Transducer: Device that emits ultrasound waves and, in some cases, receives reflections or echoes that are bounced off tissues. The transducer may send the signals to a central processing unit for translation, eg, image formation. Transducers operate as either piezoelectric or magnetostrictive.

Ultrasonic: Frequencies above the range audible to the human ear (20,000 Hz and above).

Ultrasound: Acoustic energy above human hearing. Often used to: diagnose and view structures whereby sound waves are bounced off tissues or surfaces, stimulate and heat tissue in therapy, and break up material for cleaning purposes.

Ultrasonography (sonography): Process by which high-frequency sound waves are used to develop an image of a structure. The technique measures different amounts of resistance to the sound waves and then uses the data to generate a picture. The choice of frequency is a difference between resolution of the image and imaging depth. For example, lower frequencies produce less resolution yet image deeper into the body. Ultrasonography is often used when referring to medical and dental applications of ultrasound.

fractures, spinal fusion, dental implants, periodontal defects, and in other maxillary and mandibular anomalies, in order to enhance the healing process. Furthermore, major insurance companies such Blue Cross/Blue Shield and CIGNA HealthCare now recognize the benefits of ultrasound as an adjunctive way to promote healing in certain fractures and provide coverage. The potential to stimulate bone growth and influence the reparative phase has energized both the medical and dental communities with a wide variety of

treatment considerations for oncologists, orthopedics, periodontics, and maxillofacial surgery.3,4

Parallel applications of ultrasound have transitioned into food technology; agriculture, including food production, farming, and ranching; and the shipping industry. Ultrasound is used as a rapid, noninvasive diagnostic technique to monitor food product texture and composition, identify harmful microorganisms and foreign bodies, and detect package flaws or microleaks that can cause contamination. Livestock produc-

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ers use ultrasound to evaluate the amount and depth of fat, marbling (fat percentage), and muscle on cattle in order to determine the United States Department of Agriculture (USDA) grade quality and market readiness. In the wake of intensified security, tracking shipping containers and examining cargo contents have become increasingly complex and overwhelming. As a result, ultrasound technology is currently used by the shipping and security industries to analyze the millions of containers that enter American ports annually.

Ultrasound has progressed through dramatic technological changes since its inception. Today, ultrasound has gained universal acceptance for a wide range of safe, noninvasive, diagnostic, therapeutic, and operative applications. Nevertheless teams of researchers, engineers, and clinicians continue to investigate ways to advance and incorporate ultrasound technology into a myriad of state-of-the-art procedures in medicine, dentistry, and industry.

# **ULTRASOUND COMPONENTS**

Although the function and appearance of the ultrasound imagery device may

Figure 2. Ultrasound is commonly used by obstetricians to monitor the developing fetus in a

vary depending on its application, all units are composed of three main components:

- 1. Display
- 2. Transducer
- 3. Processing unit

Producing an image from sound is accomplished in three phases. First, a sound wave is produced, the echoes are received, and then interpreted. The formation of an image from sound is a complex process whereby an image is created by determining how long it takes for the echo to reach a structure and return. The technique measures different amounts of resistance to the sound waves and then uses the data to generate a picture. The strength of the echo determines the varying shades of grey-strong echoes are white, weak echoes are black-thus producing an image in a grayscale. The processing unit interprets the returning echoes as pictures, objects, or graphs.

The transducer is the most essential component of the ultrasound device because it is responsible for emitting and receiving sound waves or echoes. Transducers are made in many different sizes and shapes depending on the purpose of the unit. Small slender transducers are used for internal views of the body, whereas the larger units are used externally to monitor large structures such as the fetus. Encased in a probe or handpiece, the transducer produces sound waves in a range of high and low frequencies. Using a coupling agent, ie, water or gel, the focused waves travel into an area of the body where they reflect against body tissues and then return to the transducer. The transducer converts the returning echoes or vibrations into electrical impulses and then transmits these to the processing unit. The time it takes for the wave to emit the sound and return is used to calculate depth, direction, and location.

### **ULTRASOUND IN** DENTISTRY

The use of ultrasound in medicine is a ubiquitous tool. However, its routine use in dentistry has not yet been realized. The transition of ultrasound to dentistry originated from the industrial application of drilling solid materials in the 1950s. For years, researchers have explored ways to apply this technology to cavity preparations. Although research is ongoing, because of problems with insufficient carious tissue removal, slow cutting speed, high cost, and the advent of the high-speed drill, the use of ultrasonic cavity preparation has never been fully developed.

Ultrasonic cleaning of dental instruments was one of the first applications of ultrasoun tistry. In 197 ultrasonic cl an automati varying the v varied the u ous commen cleaning uni a single fur constructed bers and var tal instruments. Therefore, this led to the development of ultrasonic water baths specifically designed for cleaning medical and dental instruments.

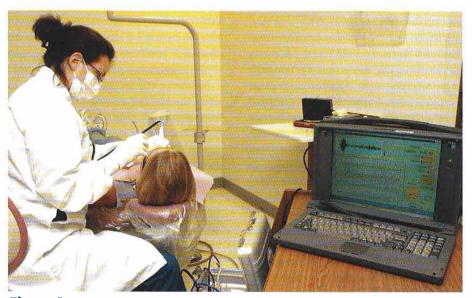


Figure 3. Ultrasound probe equipment.

The ultrasonic cleaning action created by the transducer is largely due to cavitation, which changes the surface of materials by the application of sound at extremely high intensity and frequency. It is the formation of the turbulent bubbles and their pulsation and/or collapse that produces the cleaning effect. Although debridement may occur in plain water, it is enhanced with the addition of a cleaner or surfactant.

Since the 1960s, a variety of techniques have been considered for the use of ultrasound in dentistry, yet the two main clinical areas of use remain in periadontics and endodontics. The terms between 20 kHz-42 kHz, whereas the piezoelectric device operates at between 29 kHz-50 kHz and has a linear stroke configuration. Cavitation is created in the liquid surrounding the tip, and acoustic microstreaming occurs because the fluids are rapidly agitated. The use of sonic and ultrasonic instrumentation has become a widely accepted and wellresearched modality for the effective removal of calcified deposits and disruption of biofilm.

Researchers continue to investigate ultrasound's diagnostic capabilities to image periodontal structures in order to identify and manage disease.5-7 New technologies and techniques based on ultrasound principles are being studied to determine their usefulness as a

**Power Dispersion on Tip** 

Figure 4. A diagram of the ultrasound probe in use.

periodontal assessment tool. Currently, the gold standard of periodontal assessment relies on a retrospective analysis of clinical attachment loss and radiographs. The availability of a noninvasive periodontal probe that maintains sulcus integrity and reduces operator variability has the potential to advance periodontal assessment in accuracy and patient comfort. The use of a periodontal assessment tool that could provide real-time hard and soft tissue information may change the way future clinicians diagnose and treat oral disease.

The Ultrasonographic Periodontal Probe (currently in development) has the potential to provide more accurate depth measurements than the ± 1 mm, which is generally considered to be the gold standard, while being noninvasive. Although not ready for routine clinical use, the ultrasonographic probe

one of the first applications	oddities and endoddities. The terms			
ınd technology used in den-	ultrasound and ultrasonic in dentistry			
976, a patent was issued for an	most often refer to mechanical debride-		Table 1	of powered scaling device
cleaning device adapted with	ment. Periodontal debridement results		Iddie 1. Cumpansun	s or powered scanng dearc
tic timer and a regulator for	in deposit removal through the action of			mt t t
e voltage input, which in turn,	kHz-frequency vibrating tips. The use of		Magnetostrictive	Piezoelectric
ultrasonic frequency. Previ-	magnetostrictive and piezoelectric	Optimal Frequency	20-42 kHz	29-50 kHz √ WW
ercially available ultrasonic	power scaling devices revolutionized	optimal Frequency	20-42 KHZ	29-30 KHZ IV WWW
nits were designed to perform	periodontal instrumentation (see Table			
unction and not specifically	1). The magnetostrictive scaling device,	Transducer (converts	Metal rod or stack	Ceramic
d to accommodate the num-	which has an elliptical stroke pattern,	energy to vibration)	of metal sheets	
ariations in medical and den-	operates at an optimal frequency of	Stroke Pattern	Elliptical MMMM	Linear -
nents Therefore this led to	hotwoon 20 kHz-42 kHz whereas the	Stroke Futtern	Million	Lillear

Lateral surfaces

more active

All surfaces active

red scaling devices.

combination of both.

exceptional pace.

toothbrushes have transitioned from sim-

ple mechanical models to complex, multi-

functional, high-tech versions that use

sonic and ultrasound technologies or a

Toothbrush design, individual tech-

nique, and compliance have a major

impact on the overall effectiveness of

oral care. Responding to increased

interest in improving oral health and

recognizing that most individuals

spend less time than necessary brush-

ing and flossing, toothbrush manufac-

turers looked to technology to over-

come this inadequacy. In an effort to

advance consumer self-care, the tooth-

brush industry has responded by pro-

ducing and redesigning brushes at an

The oral care market, which 50 years

ago meant only a few variations of

manual toothbrushes, has now trans-

lated into a multibillion dollar indus-

try. Although the manual toothbrush

will probably never be replaced, the

power toothbrush has increased its

market share and sparked consumer

appeal. Major companies such as Col-

gate Palmolive, New York; Philips Oral

Healthcare, Stamford, Conn; Procter &

Gamble, Cincinnati; Sunstar Americas, Chicago; and Waterpik Technologies,

Fort Collins, Colo, have proprietary

niche versions of both rechargeable

Several key clinical studies indicate

that power toothbrushes reduce plaque

and gingivitis if used as part of a regular

oral hygiene program.11-17 The Cochrane

Report revealed an expansive list of

research studies on power brushes relat-

ed to plaque removal, gingival health

improvements, benefits for specific pop-

ulations, and safety.18 The report chroni-

cled compelling evidence in favor of power brushes, specifically those with a

rotation-oscillation feature. Additional

reviews by Penick19 and the Canadian

Dental Hygienists' Association<sup>20</sup> support

the conclusions that individuals who use

power toothbrushes are more effective in

plaque removal than manual brush users.

and battery powered brushes.



may be able to characterize various aspects of gingival tissues, such as thickness, as well as detect early bone demineralization before conditions are clinically present (see Figure 3).

To operate the ultrasonographic probe, the hollow tapered tip is positioned on the gingival margin in the same orientation as a manual probe (see Figure 4). When the foot pedal is activated, a narrow beam of ultrasound energy, coupled with water, is projected into the sulcus. A transducer in the probe head transmits and detects the returning waves and then sends them to the processing unit where they are interpreted. Pocket depth is calculated by the amount of time it takes for the echo to travel to the epithelial attachment and back. Studies are underway investigating the role that disease and calcified deposits play on ultrasonographic pocket depth measurements. Additionally, researchers continue to refine sophisticated software tools that will be able to generate three-dimensional geometry of the periodontal tissues and offer real-time analysis.

Ultrasound technology has also transitioned into endodontics with the development of ultrasonic systems for internal root debridement and canal preparation.<sup>5</sup> Based on conventional magnetostrictive and piezoelectric technology, the systems provide the oscillating action of the files, coupled with acoustic microstreaming, to remove debris from root canals more thoroughly.

Ongoing research continues to explore ways to image hard tissues in order to detect cracks in teeth and carious lesions.8-10 Dental ultrasonography has the promise of providing more useful real-time diagnostic information related to tooth integrity without ionizing radiation. Typically, the diagnosis of cracked teeth depends on ruling out other possibilities rather than on direct clinical observation. However, the ability to detect cracks in teeth with an ultrasound imaging system would provide the clinician with definitive information, rather than relying on a process of elimination. Additionally, researchers continue to explore the use of an ultrasonic caries detection device to identify interproximal radiolucency without exposing patients to radiation.

Following the success of ultrasound in medicine, the future of dental ultrasound looks promising. While dental ultrasonography has been studied for more than 40 years, many opportunities remain to expand this technology for clinical applications, research, and oral care.

### POWER TOOTHBRUSH **TECHNOLOGY**

The first true electric/power toothbrush— Broxodent®—was introduced in the United States during the early 1960s by Squibb. The Interplak® followed in 1987. Power toothbrushes have evolved over the past 20 years as a result of improved technology. The first and second generations of power toothbrushes mimicked the motions of manual brushing, moving sideto-side and circular. Brushes today move in speeds and directions that are difficult to duplicate with manual brushing, thus advancing toothbrush technology far beyond expectations (Table 2). Power

A BE						
			Table 2. Variations in power toothbrushes.			
	1st Generation	2nd Generation	3rd Generation	4th Generation		
	Mechanical	Rotary	Sonic*	Sonic + Ultrasound**		
	1960s	1990s	1992	2007		
Mode of cleaning action	Side to side or up and down bristle motion	Circular, rotary, or oscillatory bristle motion (some with in and out bristle pulsation)	Rapid bristle motion (sonic), generalized fluid movement	Rapid bristle motion (sonic) with ultrasound activation of bubbles within fluid		
Frequency bristle motion	Typically 60 Hz or less	20 Hz – 75 Hz	150 Hz - 300 Hz	194 Hz		
Frequency of ultrasound	N/A	N/A	N/A	324,000 Hz		
Brush strokes and/or pulsations per minute	7,200 strokes/ min or less	2,400 - 9,000 strokes/min (some with up to 40,000 pulsations)	18,000 – 36,000 strokes/min	23,600 strokes/min		
Ultrasound cycles per minute	N/A	N/A	N/A	1,945,000 ultrasound cycles		

<sup>\*</sup>Sonic frequency: 20 Hz-20,000 Hz

SONIC TOOTHBRUSHES

A third generation of power brushes emerged based on sonic technology that offered distinct differences in motion and frequency over previous models.21,22 Sonic technology energized the power toothbrush industry with a new class of brushes with two separate mechanisms of action-mechanical cleaning plus sonic vibratory motions.

Typically, a manual toothbrush user is able to generate approximately 300 strokes per minute, whereas conventional electric (nonsonic) toothbrushes produce in the range of 2,500-7,500 strokes per minute. Sonic technology has produced a class of toothbrushes with the ability to create much higher frequency bristle action than conventional power brushes.

The sonic toothbrush head vibrates at a high rate, creating millions of tiny turbulent bubbles in the salivary fluids. It is this vibrational motion, which creates turbulent fluid dynamics, that sets the sonic brushes apart from previous generations of electric toothbrushes. The fluid shear forces generated by sonic activity have the ability to penetrate 2 mm-3 mm beyond the reach of the brush filaments, which contributes to the toothbrush's plaque removal ability.23 The rapid bristle motion that the sonic technology creates results in greater fluid movement around the toothbrush head and generates fluid forces that extend further than the tips of the bristles.

In the early 1990s, Sonicare® was the first generation of sonic brushes brought to the market by Optiva Corp. In 2000, Philips acquired Optiva and in January 2001, Optiva Corp was changed to Philips Oral Healthcare Inc. According to company statistics, by the end of 2001, Sonicare became the number one rechargeable power toothbrush in the United States.24 Since the introduction of Sonicare, a variety of power brushes have appeared, with sonic technology. Waterpik introduced the Sensonic in 1994 and subsequently, various other brushes have emerged. Sold in stores, on television, and via the Internet,

there are numerous sonic toothbrush models with claims of product superiority; even devices that suggest they will turn an ordinary toothbrush into a sonic cleaning machine with a sonic pulse adapter.

**Ultrasound Technology** 

With the abundance of powered toothbrushes and devices available, individuals need to be vigilant to research products carefully since many companies provide little or no scientific evidence to support claims. One of the most confusing aspects of plowing through the information on power toothbrushes is the difference between features and terms such as sonic, ultrasonic, and ultrasound. Technically all sonic, ultrasonic/ultrasound toothbrushes can be termed sonic because they use acoustic energy. However, differences are determined by the mode of action, frequency, strokes per minute, and vibrations (Table 2).

Consumers and dental professionals need to consider the evidence in order to understand the technology differences when purchasing or recommending a power toothbrush.

### **ULTRASOUND TOOTHBRUSHES**

The long and wide-ranging history of ultrasound has recently transitioned into oral care. The examination of patents dating back to the mid-1900s provides evidence that the idea of using ultrasound in a power toothbrush has been around for some time, but very few have been commercially available and none have gained significant market share. Relatively recent advancements in piezoelectric and electronic drive technology have allowed miniaturization of the ultrasound components so they can be conveniently incorporated within the size and ergonomic constraints of a rechargeable power toothbrush.

A fourth generation of powered toothbrushes has been developed that combines ultrasound and sonic technologies. Ultrasound toothbrushes incorporate a transducer that operates at very high frequen-

<sup>\*\*</sup>Ultrasound frequency: ≥ 20,000 Hz



"...studies indicate

toothbrushes

gingivitis."

cies (>20,000 Hz), differentiating these brushes from sonic devices that use frequencies of 20 Hz-20,000 Hz. As ultrasound passes through fluids, it produces cavitation and creates a stirring action called acoustic streaming. It is this collective action that is designed to create optimal cleaning. The bristle that **power** action of power brushes with both the sonic and ultrasound creates milreduce plague and lions of bubbles. It is the ultrasound that provides a separate characteristic independent of the motion of the bristles that transforms these into pulsating bubbles.

Marketed in the 1990s, the Ultra-Sonex<sup>TM</sup> represented the first power toothbrush to combine dual frequency ultrasound and sonic technology.25-27 The UltraSonex also provides a model that employs fewer strokes for individuals who have sensitive teeth, as well as an ultrasound only version for those who prefer no sonic action.

The Ultreo<sup>TM</sup>, officially launched in February 2007, is the second power toothbrush to reach the marketplace that uses ultrasound technology. The impetus for developing the Ultreo toothbrush began with Pierre Mourad, MS, PhD, a physicist at the University of Washington. Mourad has a wealth of expertise in ultrasound and its ability to transform bubbles to produce mechanical energy. A power toothbrush user, he theorized that the bubbles created by mechanical movement of the bristles could be transformed into pulsating bubbles that would enhance plaque biofilm removal. What began as a theory was verified through concept testing in the laboratory, and after 4 years of development and research, Ultreo the ultrasound toothbrush was introduced to dental professionals.

Ultreo combines ultrasound waveguide technology with sonic bristle action for optimal synergy. The waveguide technology channels ultrasound energy from the transducer into the bubbles to produce cavitational effects, which disrupt biofilm without bristle contact. Focusing on the areas that bristles cannot reach, the

> Ultreo designers selected an ultrasound frequency to target bub-

bles 50 µm in diameter, much smaller than a typical toothbrush bristle, which is typically 150 µm in diameter.

An in vitro study performed by Roberts, Hacker, Oswald, and McInnes for Ultreo, was designed to evaluate the ability of com-

bined sonic and ultrasound technology to remove biofilm from model dental surfaces. Streptococcus mutans was chosen as a model dental plaque microorganism and grown on either hydroxyapatite (HA) discs or on frosted glass slides with imbedded grooves.

The Ultreo was compared to: a sonic only brush, an oscillating brush, or a control (Ultreo with ultrasound disabled). HA discs were positioned 3 mm from the bristle tips and the grooved slides were exposed to direct bristle contact, both within a dentifrice slurry. All brushes were activated for 5 seconds. Image analysis of *S. mutans* present on the HA disks after treatment revealed significantly more S. mutans biofilm removal with the Ultreo than with the sonic, oscillating, and control treatments. Visual examination of fluorescent-stained S. mutans present on the glass slides revealed that bristle action of all treatments removed biofilm from the flat surfaces. However, only treatment with Ultreo removed substantial biofilm from within the grooves. This research demonstrated that the combined ultrasound and sonic technology removed significantly more S. mutans biofilm from HA discs without bristle contact, a simulation of plaque bacteria removal in hard-to-reach areas.

A subsequent in vivo study, done for Ultreo by Sharma, Qaqish, Galustians, and Ortblad, was conducted to evaluate plaque removal of the Ultreo. In a two visit experiment, 33 participants were assigned to brush for either 1 or 2 minutes. Data revealed that the percentage of plaque reduction for full mouth plague was 86.0% and 87.6%, after 1 and 2 minutes of brushing, respectively. The percentage of plaque reduction from difficult-to-reach proximal areas was 95% and 97%, after 1 and 2 minutes, respectively. All reductions in plaque removal were significant.

The development of a new generation of power toothbrush that utilizes combined ultrasound and sonic technologies represents a novel approach to oral care.

### SAFETY

Ultrasound is considered a safe technology. Acoustic output from ultrasound devices are regulated by the United States Food and Drug Administration (FDA) and monitored by international regulatory agencies such as the National Council on Radiation Protection and Measurements<sup>28</sup> and the World Federation for Ultrasound in Medicine and Biology.29 These groups represent experts who provide safety guidelines and make recommendations to protect the public.

Generally, researchers and dental professionals agree that the daily use of power toothbrushes is at least as safe as manual brushes on soft and hard tissues. A comprehensive review of manual versus sonic and ultrasonic toothbrushes revealed that high frequency toothbrushes are considered safe.22 Consumers should be confident in knowing that when used properly power toothbrushes will cause no more safety concerns than manual brushes.20 The safety of Ultreo and Sonicare with respect to wear and damage to the soft and hard tissues, as well as to cements and restorative materials, has been validated.13-17,30,31

Power toothbrush manufacturers typically test for compliance with safety standards for electromagnetic devices. As all devices with motors and charge coils produce some level of electromagnetic energy, if users have any concerns regarding usage of any power toothbrush with a pacemaker or other implanted device, they should contact their physician or the implant device manufacturer prior to use.

### DISCUSSION

Looking back on 100 years of ultrasound technology, coupled with prospects for the future, an extraordinary roadmap emerges. The foundation of ultrasound was laid in the 1800s with remarkable advances in technology since that time.

The transition from military and industrial applications of ultrasound to medicine generated a wide variety of diagnostic and therapeutic applications. The realignment of ultrasound technology to dentistry emerged in devices that range from simple cleaning units to power scalers, to oral care, and beyond.

America is becoming a technology nation with many people switching to power toothbrushes as a means for improving their oral care. IPods now deliver oral care information and reminders to consumers, while power toothbrushes have transitioned from the simple mechanical devices to generations of sonic, ultrasonic, and ultrasound brushes. Most toothbrush manufacturers have a proprietary version that separates their product from another, however, consumers want the best brush possible that blends the most current technology with exceptional performance. The competition in the power toothbrush industry is fierce, yet it will eventually be the consumer who determines which toothbrushes thrive and which ones are squeezed out of the marketplace. Keeping up with emerging technology, the use of ultrasound has inspired a new generation of toothbrushes that have the potential to move oral care far beyond current capabilities. C

**Ultrasound Technology** 

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### 1. The scientific study of sound that includes vibrations or frequencies above human hearing is referred to as:

- A. acoustics
- B. cavitation
- C. metal flaw detection
- D. SONAR

### 2. A unit of frequency related to one cycle per second is referred to as:

- A. density
- B. hertz
- C. kilovoltage
- D. milliampere

### 3. Many people consider be the father of ultrasound.

- A. Alfred T. Black
- B. Karl T. Dussik
- C. Ludwig G. Ian
- D. Randolph A. Hailey

### 4. A typical manual toothbrush user is able to generate approximately strokes per minute.

- A. 100
- B. 200
- C. 300
- D. 400

### 5. Clinical studies indicate that when used properly power toothbrushes are as safe as manual toothbrushes.

- A. T
- B. F

### 6. The first true electric/power toothbrush was introduced to the United States marketplace during the

- A. 1950s
- B. 1960s
- C. 1970s D. 1980s

### 7. Sonic frequencies range between:

- A. 20 20,000 Hz
- B. 30 30,000 Hz
- C. 40 40,000 Hz
- D. 50 60,000 Hz

### 8. Sonic technology increases brush strokes and/or pulsations to approximately per minute.

- A. 1,000 or less
- B. 5,000 7,200
- C. 18,000 36,000 D. 50,000 or more

### 9. Which of the following power toothbrushes was considered to be the first generation of sonic brushes?

- A. Crest Spin Brush
- B. Oral B Vitality
- C. Sensonic
- D. Sonicare

### 10. The 4th generation of powered toothbrushes developed combines which of the following technologies?

- A. cybersonic and ultrasound
- B. manual and sonic
- C. manual and ultrasonic
- D. ultrasound and sonic

### 11. Which of the following power toothbrushes is representative of a 4th generation powered toothbrush?

- A. Sonicare
- B. Ultreo
- C. Oral-B
- D. Rota-dent

### 12. The main difference between sonic and ultrasound technology is the:

- A. frequency of the acoustic wave
- B. speed of the processing unit
- C. size of the transducer
- D. variation in display panel

### 13. The formation of an ultrasound image is created by how long it takes the ultrasound wave to reach a structure, echo off the structure, and return to the processing unit.

### 14. Ultrasound used within a power toothbrush is able to generate cycles per minute:

- A. 7,200
- B. 20,000
- C. 324,000 D. 1,945,000
- 15. The purpose of the waveguide in the Ultreo is to channel ultrasound from the transducer into the bubble population in the mouth to produce cavitation.
- A. T

### 16. Ultrasound operates at frequencies of

Hz.

- A. 5,000 7,000 B. 7,500 - 10,000
- C. 10,000 15,000
- D. >20,000

### 17. The application of ultrasound may be found in the following products within a dental office:

- A. scalers/debridement
- B. dental instrument cleaners
- C. power toothbrushes
- D. all of the above

# 18. Within a power toothbrush, the ultrasound is designed to cause bubbles

- A. are destroyed
- B. separate according to size
- C. pulsate
- D. spin rapidly about their axis

### 19. To access areas that bristles cannot reach. Ultreo is designed to target bubbles smaller in diameter than a typical toothbrush bristle.

- A. T
- B. F

### 20. Research demonstrates that combing ultrasound and sonic technology significantly removed S. mutans from:

- A. hydroxyapatite disks without bristle contact
- B. dental water lines
- C. dorsum of the tongue surface
- D. x-ray units

### Filed 10/26/2007 **Answer Sheet** Page 7 of 8

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